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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/645,540	08/22/2003	Atsushi Tachino	241908US0	8107

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EXAMINER

HINES, JANA A

ART UNIT PAPER NUMBER

1645

DATE MAILED: 06/16/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/645,540

Applicant(s)

TACHINO, ATSUSHI

Examiner

Ja-Na Hines

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 20 January 2004.
2a) ☐ This action is FINAL. 2b) ☐ This action is non-final.
3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-11 is/are pending in the application.
4a) Of the above claim(s) _____ is/are withdrawn from consideration.
5) ☐ Claim(s) _____ is/are allowed.
6) ☐ Claim(s) _____ is/are rejected.
7) ☐ Claim(s) _____ is/are objected to.
8) ☒ Claim(s) 1-11 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

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DETAILED ACTION

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
 - I. Claims 1-2 and 4-5 are drawn to a pretreatment kit comprising sodium hydroxide, tartaric acid and a nonionic surface active agent, and method for saliva in the identification and quantification of *Streptococci mutans*, classified in class 436, subclass 825.
 - II. Claims 6-7 are drawn to a method for saliva in the identification and quantification of *Streptococci mutans*, comprising sodium hydroxide, tartaric acid and a nonionic surface active agent in an amount of 5 to 25% by weight, classified in class 436, subclass 825.
 - III. Claims 8-9 are drawn to a method for saliva in the identification and quantification of *Streptococci mutans*, comprising sodium hydroxide, tartaric acid in an amount of 5 to 25% by weight, and a nonionic surface active agent, classified in class 530, subclass 413.
 - IV. Claims 3-5 and 10-11 are drawn to a pretreatment kit comprising sodium hydroxide, tartaric acid, a nonionic surface active agent and tris(hydroxymethyl) aminomethane and a pretreatment method for saliva in the identification and quantification of *Streptococci mutans*, classified in class 435, subclass 7.34.
2. The inventions are distinct, each from the other because of the following reasons:

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Inventions I, II, III and IV are related as distinct methods because they are different methods with different method steps; reagents; functions and those result in different final outcomes. First, the instant specification does not disclose that these methods would be used together, rather the specification beginning at page 9 states that the methods are separate and distinct. The methods are all unrelated as they comprise distinct steps and utilize different products which demonstrate that each method has a different mode of operation. Each invention performs this function using a structurally and functionally divergent material. Moreover, the methodology and materials necessary for the pretreatment of saliva differ significantly. For instance, the use of a specific amount of the nonionic surface active agent is necessary to solubilize surface proteins on *Streptococci mutans*, and such solubilization may not be necessary to practice the other methods. Similarly, the specification teaches that tartaric acid in an amount of 5 to 25% by weight is necessary to impair antigens of *Streptococci mutans*. In this case, group IV is separate and distinct, from groups I-III, since only group IV additionally comprises tris(hydroxymethyl) aminomethane. Therefore, each method is divergent with respect to the amounts of reagents used and their associated steps. For these reasons the inventions I, II, III and IV are patentably distinct.

Furthermore, searching the inventions of groups I-IV would impose a serious search burden. The inventions have a separate status in the art as shown by their different classifications. A pretreatment kit and method sodium hydroxide, tartaric acid, a nonionic surface active agent and tris(hydroxymethyl) aminomethane require a different search, than the other methods. Thus, a search drawn to a pretreatment kit

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and method sodium hydroxide, tartaric acid, a nonionic surface active agent and tris(hydroxymethyl) aminomethane is not necessary for a determination of novelty and unobviousness of the method of group II which comprises sodium hydroxide, tartaric acid and a nonionic surface active agent in an amount of 5 to 25% by weight.

Furthermore, the method comprising sodium hydroxide, tartaric acid in an amount of 5 to 25% by weight, and a nonionic surface active agent may be known even if the method of group IV is novel. In addition, the technical literature search for the pretreatment kit and method of group I and the pretreatment kit of group IV are not coextensive, since the kit of group I may be characterized in the technical literature prior to discovery of the kit of group IV.

3. Furthermore, the distinct steps and products require separate and distinct searches. The inventions of Groups I-IV have a separate status in the art as shown by their different classifications. As such, it would be burdensome to search the inventions of Groups I-IV together.

4. Because these inventions are distinct for the reasons given above, have acquired a separate status in the art as shown by their different classification, and the search required for each group is not required for the other groups because each group requires a different non-patent literature search due to each group comprising different products and/or method steps, restriction for examination purposes as indicated is proper.

5. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

6. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ja-Na Hines whose telephone number is 571-272-0859. The examiner can normally be reached on Monday-Thursday and alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith can be reached on 571-272-0864. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Ja-Na Hines
June 1, 2005

